

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-451V

UNPUBLISHED

CHERI SLEETH,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: November 10, 2021

Special Processing Unit (SPU);
Entitlement to Compensation; Ruling
on the Record; Findings of Fact;
Onset; Influenza (Flu) Vaccine;
Shoulder Injury Related to Vaccine
Administration (SIRVA)

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for petitioner.

Laurie Wiesner, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT AND RULING ON ENTITLEMENT¹

On March 27, 2019, Cheri Sleeth filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a shoulder injury related to vaccine administration (“SIRVA”) caused by an influenza (“flu”) vaccine administered on October 6, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that there is a preponderance of evidence that the onset of Petitioner's injury (specifically shoulder pain) occurred within 48 hours of his vaccination. I otherwise find that Petitioner is entitled to compensation for a left SIRVA.

I. Relevant Procedural History

This case was initiated on March 27, 2019. Initially, Respondent indicated a willingness to engage in settlement discussions, but the parties reached an impasse, and on April 8, 2021, Respondent filed a Rule 4(c) Report. ECF No. 41, Respondent's Rule 4(c) Report ("Report"). Respondent opposed compensation, arguing in part that Petitioner has failed to establish a Table claim because the records did not established onset within 48 hours of Petitioner's vaccination. Report. at 6-7.³

Petitioner filed a Motion for a Ruling on the Record on May 24, 2021, in support of her claim. Petitioner's Motion for Ruling on the Record Regarding Entitlement ("Mot."), ECF No. 43. Respondent filed a status report on July 6, 2021, stating that onset is the only Table criteria that Respondent believes has not been met. ECF No. 45. Respondent further stated that he has no additional arguments other than those set forth in his prior Rule 4(c) Report. *Id.* This matter is now ripe for resolution.

II. Petitioner's Medical Records

Ms. Sleeth received a flu vaccine on October 6, 2016 in her left shoulder. Ex. 1 at 1. Almost four weeks later, on November 1, 2016, Petitioner presented to Dr. Massari with complaints of left shoulder and arm pain, and decreased range of motion. Ex. 2 at 2-4. Petitioner stated that she "[g]ot a flu shot 1 month ago. Her shoulder, arm is sore...." *Id.*

A month later, Petitioner saw Dr. David Buchalter, an orthopedic surgeon, on December 13, 2016. Ex. 4 at 81-83. Dr. Buchalter's records state the onset was "09-06-16", however it also states "Context: 10-06-16". *Id.* at 82. Petitioner received a corticosteroid injection and was referred to physical therapy. *Id.* at 83. Then, on December 20, 2016, Petitioner had her initial physical therapy consultation. Ex. 4 at 78-80. Petitioner reported her left shoulder "has been bothering her since she received a flu shot in October." *Id.* at 78. The records also state that Petitioner sustained left shoulder pain and limited range of motion "after receiving a flu shot...." *Id.* at 80.

³ Respondent also argues that Petitioner has not established causation-in-fact. Report at 7-8.

Petitioner had a follow-up appointment with Dr. Buchalter on January 24, 2017. At that time, the date of onset was noted as October 6, 2016. Ex. 4 at 61. She underwent an MRI on January 27, 2017, which noted that she had “[l]eft shoulder pain with decreased range of motion since having flu shot 10/6/16....” Ex. 4 at 88 (emphasis added). The MRI showed a partial thickness tear of the supraspinatus tendon, mild subacromial subdeltoid bursitis, and tendinosis of the rotator cuff tendons. *Id.*

Petitioner saw Dr. Buchalter again on February 7, 2017. At that time, the date of onset was indicated as October 6, 2016, the timing was described as acute, and it was specifically linked to her flu shot, stating “Context: 10-06-16 [patient] had flu shot....” Ex. 4 at 56-58. Later that same month, Petitioner underwent arthroscopic surgery with Dr. Buchalter. Ex. 4 at 52-55. Thereafter, Petitioner completed a round of physical therapy. Ex. 4 at 3-4.

There is a subsequent two-year records gap. In 2019, Petitioner saw Dr. Buchalter on two occasions and completed another round of physical therapy for left shoulder pain. Ex. 12 at 62-64 (October 7, 2019 follow-up record with Dr. Buchalter for left shoulder pain); Ex. 12 at 59-60 (October 10, 2019 record from physical therapy provider indicating left shoulder continues to have some symptoms, pain, and discomfort); Ex. 12 at 7-9 (November 11, 2019 visit with Dr. Buchalter indicating Petitioner still has some “annoying achy pain when reaching behind and sleeping on the shoulder”).

III. Affidavit Evidence

Ms. Sleeth submitted an affidavit in support of her petition on April 1, 2019. Ex. 7. In it, she states that she received a flu vaccine in the morning of October 6, 2016. By noon of that day, she states that her arm began hurting, and the pain felt progressively worse throughout the afternoon. *Id.* at 2. Petitioner also states that she had trouble sleeping that night due to the pain, and the next morning her shoulder continued to hurt. *Id.* at 2-3.

IV. Parties’ Arguments

Respondent argues that Petitioner has failed to show she suffered a Table claim because onset of her pain was not within 48 hours of his vaccination. Report at 6-7; ECF No. 45. Respondent notes that Petitioner’s medical records do not establish a definite date of onset for her symptoms, and otherwise employ vague phrases that make it difficult to determine whether her pain likely began within 48 hours after her vaccine. *Id.* at 7. Respondent further argues that Petitioner has not established a causation-in-fact claim. *Id.* at 7-8.

Petitioner requests that I issue a ruling finding that she is entitled to compensation in this case. Mot. at 1. She avers that she meets the requirements for a SIRVA as described in the Vaccine Injury Table, and thus is entitled to a presumption of causation. Mot. at 4-5.

V. Fact Findings and Ruling on Entitlement

At issue is whether Petitioner meets the requirements for a SIRVA as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation (“QAI”). Specifically, the parties dispute whether Petitioner’s symptoms (specifically pain) occurred within 48 hours. 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the duration and severity of petitioner’s injury, and the lack of other award or settlement,⁴ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

⁴ In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

The United States Court of Federal Claims has also recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also

be determined. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

A. Factual Findings Regarding QAI Criteria for Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence supports each of the QAI requirements for a Table SIRVA.

1. Petitioner has no Prior Left Shoulder Condition or Injury

The first requirement under the QAIs for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent has not contested that Petitioner meets this criterion, and I find that she has demonstrated a lack of history of pain, inflammation, or dysfunction of her left shoulder that would explain his symptoms. *See Ex. 2 at 14-16* (records from the period prior to Petitioner’s vaccination that include no history of prior shoulder pain).

2. Onset of Petitioner’s Injury was within Forty-eight Hours of her Flu Vaccination

I find that, based on preponderant evidence, onset of Petitioner’s injury was within 48 Hours of her flu vaccination. The following finding of fact is based on a complete review of the record, including all medical records, affidavits, and additional evidence filed. Specifically, I highlight the following:

- Petitioner received a flu vaccination in her left shoulder on October 6, 2016. Ex. 1 at 1.
- On November 1, 2016, Petitioner complained of left shoulder pain. Ex. 2 at 2-4. Dr. Massari's records indicate that Petitioner affirmatively linked her shoulder pain to the flu vaccine, noting "Got a flu shot 1 month ago. Her shoulder, arm is sore...." Ex. 2 at 2-4.
- Petitioner reported continued shoulder pain on December 13, 2016 to Dr. Buchalter, whose records also affirmatively link her shoulder pain to the October 6, 2016 flu vaccine. See Ex. 4 at 81-82 (stating under "Context: 10-06-16 [patient] had flu shot").
- On December 20, 2016, Petitioner began physical therapy and reported "her [left] shoulder has been bothering her since she received a flu shot in October...she sustained [left] shoulder pain and limited [range of motion] after receiving a flu shot". Ex. 4 at 78-79.
- On January 27, 2017, Petitioner had an MRI, which noted that she had "[l]eft shoulder pain with decreased range of motion since having flu shot 10/6/16...." Ex. 4 at 88

Based on the above, the preponderance of the evidence supports a finding that onset of Petitioner's injury was within 48 hours of his October 6, 2016 flu vaccine. Even if the initial record evidence of Petitioner's first complaint of shoulder pain is a bit vague, it is not *inconsistent* with her contentions, and her witness statement is also reasonably taken into account. All other records thereafter consistently identify onset as immediately after vaccination.

3. Petitioner's Pain was Limited to her Left Shoulder

The third requirement under the QAIs for a Table SIRVA is that Petitioner's pain and recued range of motion is limited to the shoulder in which she received a vaccine. 42 C.F.R. § 100.3(c)(10)(iii). Respondent has not contested that Petitioner meets this criterion, and I find that she has demonstrated pain and reduced range of motion only in her left shoulder. See Ex. 4 at 80 (reporting only left shoulder pain since she received her flu shot).

4. There is No Evidence of Another Condition or Abnormality

The last QAI criteria for a Table SIRVA states that there must be no other condition or abnormality which would explain a petitioner's current symptoms. 42 C.F.R. §

100.3(c)(10)(iv). Respondent has not contested that Petitioner meets this criterion, and there is no evidence in the record to the contrary. Thus, the record contains preponderant evidence establishing that there is no other condition or abnormality which would explain the symptoms of Petitioner's left shoulder injury.

B. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received flu vaccine intramuscularly in her left shoulder on October 6, 2016 in Maryland. Ex. 1 at 1; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for her injury. Ex. 8 at 2; Section 11(c)(1)(E) (lack of prior civil award).

As stated above, I have found that the onset of Petitioner's left shoulder pain was within 48 hours of vaccination. See 42 C.F.R. § 100.3(c)(10)(ii) (setting forth this QAI requirement). This finding also satisfies the requirement that Petitioner's first symptom or manifestation of onset occur within the time frame listed on the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(XIV)(B) (listing a time frame of 48 hours for a Table SIRVA following receipt of the influenza vaccine). Therefore, Petitioner has satisfied all requirements for a Table SIRVA.

The last criteria which must be satisfied by Petitioner involves the severity of her SIRVA. For compensation to be awarded, the Vaccine Act requires that a petitioner suffer the residual effects of his or her left shoulder injury for more than six months or that her condition resulted in inpatient surgical intervention. See Section 11(c)(1)(D)(i), (iii) (statutory severity requirement). The records demonstrate, and Respondent does not contest, that Petitioner suffered the residual effects of his shoulder injury for more than six months and underwent surgical intervention. See, e.g., Ex. 4 at 52-55; Ex. 12 at 62-64. Thus, this requirement is also met.

Based upon all of the above, Petitioner has established that she suffered a Table SIRVA. Additionally, she has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

VI. Conclusion

In view of the evidence of record, I find that there is preponderant evidence that the onset of Petitioner's injury, specifically shoulder pain, was within 48 hours

of her vaccine. Further, based on the evidence of record, I find that Petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran

Chief Special Master